



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,727	12/05/2005	Farid Vaghefi	34074.0002.2/07.1005	4206
61214	7590	10/29/2010		
Fox Rothschild, LLP Elan Pharma International Limited 997 Lenox Drive, Bldg. #3 Lawrenceville, NJ 08648				
EXAMINER				
ROYDS, LESLIE A				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
10/20/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

### Office Action Summary

**Application No.**

10/528,727

**Applicant(s)**

VAGHEFI ET AL.

**Examiner**

Leslie A. Royds

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5, 7, 9, 11-24 and 27-40 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 and 27-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 7, 9, 11, 24 and 40 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 24 Nov 09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

**Claims 1, 4-5, 7, 9, 11-24 and 27-40 are presented for examination.**

Applicant's Amendment and Information Disclosure Statement (IDS) filed November 24, 2009 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08A (two pages total), the Examiner has considered the cited references.

Claims 1, 4-5, 7, 9, 11-24 and 27-40 are pending. Claim 25 is cancelled. Claims 12-23 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 27-40 are newly added. Claims 1, 4-5, 7, 9 11 and 24 are amended.

Applicant's arguments, filed November 24, 2009, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

#### ***Withdrawal of Newly Added Claims 27-39: Election by Original Presentation***

Applicant's amendment to add new claims 27-39 has been carefully considered in light of the subject matter that was elected and examined in the previous non-final Office Action.

The MPEP states at §819:

"The general policy of the Office is not to permit the Applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter."

Newly submitted claims 27-39 are directed to a patentably distinct product from the invention originally claimed and elected for examination for the following reasons: newly added claims 27-32 are directed to a hard gelatin capsule composition, which encapsulates a plurality of immediate-release microspheres of a hydrophobic polymer matrix with an active ingredient capable of abuse present therein in an amount sufficient to provide a specific  $T_{max}$  of 2-4 hours; with a plurality of controlled-release

Art Unit: 1614

microspheres of a water-insoluble organic matrix that resists dissolution or acidic degradation that at 50-800 microns, with an active ingredient capable of abuse therein, which are coating with methylmethacrylate or ethylcellulose, and further wherein the active ingredient is released such that blood plasma concentrations are maintained from 8-24 hours; and newly added claims 33-39 are directed to a polymeric matrix material mixed with an aliphatic alcohol, in combination with particles of an active ingredient capable of abuse with a water-insoluble controlled release coating that are chemically bonded to the matrix; whereas the claims as originally provided and elected for examination were directed to a composition comprising coated particles of an active compound capable of abuse.

The inventions are distinct because they are directed to distinct products, which can be shown to be distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, each of compositions have distinct chemical, physical and structural arrangements and functional properties unique to each product as a result of the distinct and unique chemical, physical and structural formulations employed in each product such that they are not used together, are not related, have a different design (i.e., structure) and do not overlap in scope. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since Applicant has received an action on the merits for the originally presented and elected invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-39 are withdrawn from consideration as being directed to a non-elected invention. Please see 37 C.F.R. 1.142(b) and MPEP §821.03. As stated in the MPEP at §818.02(a), "The claims originally presented and acted upon by the Office on their merits determine the invention elected by an Applicant in the application, and in any request for continued examination (RCE) which has been

Art Unit: 1614

filed for the application. Subsequently presented claims to an invention other than that acted upon should be treated as provided in MPEP §821.03.”

***Objection to the Claims (New Grounds of Objection)***

Claim 9 is objected to for reciting “and wherein the composition does not include an antagonist of the water soluble compound capable of abuse” because such a limitation has already been provided for in instant claim 1, from which instant claim 9 depends, and, therefore, is a redundant limitation. Correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 7, 9, 11, 24 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the specification and claims as originally filed fail to provide clear written description for the newly added limitations directed to (1) wherein the water soluble compound capable of abuse is an opioid agonist (claim 1); (2) wherein the composition does not include an antagonist of the water soluble compound capable of abuse (claim 1); (3) that the viscoelastic polymer is non-erodible at pH less than about 6 or is erodible in the presence of bile salts and lipase (claims 4-5); or (4) that the viscoelastic polymer is a triglyceride wax selected from the group consisting of a hydrogenated

Art Unit: 1614

cottonseed oil wax, a partially hydrogenated soybean oil, carnauba wax or a mixture thereof (claim 40).

Regarding the limitation directed to wherein the water soluble compound capable of abuse is an opioid agonist (claim 1), the instant specification recites a number of specific species of compounds capable of abuse that may be employed as the active water-soluble compound capable of abuse to be incorporated into the instantly claimed abuse-resistant pharmaceutical composition (e.g., fentanyl, sufentanil, carfentanil, lofentanil, etc.). However, the disclosure of specific species of compounds, wherein albeit some of the disclosed compounds may very well function as opioid agonist(s), fails to provide clear written support to now claim the use of any generic opioid agonist *per se* that was not previously disclosed, either explicitly or implicitly, by the specification and/or claims as originally filed. The specific disclosure of the various species of compound(s) fails to provide clear support to then broaden the claim to read upon the use of any opioid agonist *per se*. This newly added limitation represents a clear broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Regarding the limitation directed to wherein the composition does not include an antagonist of the water soluble compound capable of abuse (claim 1), the instant specification fails to recite any description or limitation directed to the specific exclusion of an antagonist of the water soluble compound capable of abuse. In fact, the specification and/or claims are silent as to the inclusion or exclusion of such a compound and, therefore, fail to provide clear written support to claim an embodiment of the instant abuse-resistant pharmaceutical composition wherein an antagonist of the water soluble compound capable of abuse is not permitted as a component of the composition. This newly added limitation represents a clear narrowing of the subject matter both claims and disclosed in the specification and claims as originally filed that is not adequately supported by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Regarding the limitation directed to wherein the viscoelastic polymer is non-erodible at pH less than about 6 or is erodible in the presence of bile salts and lipase (claims 4-5), the instant specification states at para.[0058], "In another embodiment, the opiate component is chemically bonded to the matrix...Those embodiments in which highly cross-linked polymers are used as the matrix, the tenacity of the composition is due to the hardness of the matrix. In alternative embodiments in which low cross-linked polymers or viscoelastic polymers are used as the matrix, the tenacity of the composition is due to the elasticity of the matrix. In these embodiments, matrix tenacity, or resistance to opiate component release, is imparted to the composition by the use of pharmaceutically acceptable cross-linked polymers such as cholestyramine resin." The specification further states at p.12, 1.11-13, that, "A preferred matrix material is non-erodible at pH less than 6. A further preferred aspect of the abuse-resistant composition comprises a matrix material that is erodible in the presence of bile salts and lipase."

While such disclosure has been fully and carefully considered, the instant specification clearly discloses the use of a viscoelastic polymer as one type of possible matrix material to be employed in the claimed abuse-resistant pharmaceutical composition and discloses other preferred matrix materials as those that are (i) non-erodible at pH less than about 6 or (ii) erodible in the presence of bile salts and lipase. However, the disclosure of each of these options as alternative types of matrix materials fails to provide clear written support to now claim that the water-insoluble matrix material is both a viscoelastic polymer *and* non-erodible at pH less than about 6 or both a viscoelastic polymer *and* erodible in the presence of bile salts and lipase. The specific disclosure of each of these species as alternative matrices fails to provide clear support to then narrow the claims to require that the matrix material have the characteristics of both types of matrix materials described. This newly amended limitation represents a clear narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention.

Regarding the limitation directed to wherein the viscoelastic polymer is a triglyceride wax selected from the group consisting of a hydrogenated cottonseed oil wax, a partially hydrogenated soybean oil, carnauba wax or a mixture thereof (claim 40), the instant specification clearly discloses the use of triglyceride waxes as the water-insoluble matrix material, including hydrogenated cottonseed oil wax or partially hydrogenated soybean oil, and further discloses the use of *per se* waxes including carnauba wax. See p.13-14 of the instant specification. While it is noted that the instant specification clearly discloses the use of a viscoelastic polymer as one type of possible matrix material to be employed in the claimed abuse-resistant pharmaceutical composition and discloses other matrix materials as (i) triglyceride wax in the form of hydrogenated cottonseed oil wax or (ii) triglyceride wax in the form of partially hydrogenated soybean oil or (iii) carnauba wax, the disclosure of each of these options as alternative types of matrix materials fails to provide clear written support to now claim that the water-insoluble matrix material is both a viscoelastic polymer *and* is (i) triglyceride wax in the form of hydrogenated cottonseed oil wax or (ii) triglyceride wax in the form of partially hydrogenated soybean oil or (iii) carnauba wax. The specific disclosure of each of these species as alternative matrices fails to provide clear support to then narrow the claims to require that the matrix material have the characteristics of both types of matrix materials described (e.g., both viscoelastic and a triglyceride wax, etc.) This newly added limitation represents a clear narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention. Note, further, that the instant specification fails to provide any description of the use of mixtures of any of the disclosed and/or claimed waxes as presently recited in instant claim 40.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed



Art Unit: 1614

to provide the necessary teachings, by describing the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of (1) wherein the water soluble compound capable of abuse is an opioid agonist (claim 1); (2) wherein the composition does not include an antagonist of the water soluble compound capable of abuse (claim 1); (3) that the viscoelastic polymer is non-erodible at pH less than about 6 or is erodible in the presence of bile salts and lipase (claims 4-5); or (4) that the viscoelastic polymer is a triglyceride wax selected from the group consisting of a hydrogenated cottonseed oil wax, a partially hydrogenated soybean oil, carnauba wax or a mixture thereof (claim 40).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

***Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Instant claim 1 specifies that the active water soluble compound to be incorporated into the abuse-resistant controlled-release pharmaceutical composition is an opioid agonist. However, instant claims 7 and 24 state that the compound is a narcotic. While it may be true that some opioid agonist may also be considered "narcotic agents", the two terms are not necessarily coextensive and, as a result, render the scope of the claims indefinite because it is unclear as to whether the active water soluble compound is intended to be either an opioid agonist or a narcotic agent or an opioid agonist that is also a narcotic agent. As a result of this ambiguity in the claims, the metes and bounds of the claim are not clearly set

Art Unit: 1614

forth and, therefore, do not reasonably apprise one of ordinary skill in the art at the time of the invention of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

***Claim Rejections - 35 USC § 103 (New Grounds of Rejection)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 9, 11, 24 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain et al. (U.S. Patent No. 3,402,240; 1968).

Cain et al. teaches a tablet formulation containing a predetermined amount of a therapeutic active agent or drug to be administered to a patient and functions to release a small but therapeutically effective portion of the agent or drug and thereafter continue to slowly and gradually release the agent or drug over many hours (i.e., "controlled release" as required by instant claim 1; col.1, l.10-16), wherein the tablet contains a matrix that is substantially insoluble in gastric and intestinal juices, a therapeutically bland or

Art Unit: 1614

inert filler or extender and an active therapeutic agent or drug, further wherein the matrix is, *inter alia*, carnauba wax (i.e., which is equivalent to Applicant's instantly claimed "viscoelastic polymer" as defined in instant claim 40, which constitutes the "water-insoluble matrix material" as recited in instant claim 1; col.1, 1.31-37). Cain et al. teaches that the therapeutic agent may be selected from, *inter alia*, alkaloid compounds, such as, *inter alia*, dihydrocodeinone bitartrate (col.3, 1.3). Cain et al. discloses that the finished tablets comprise the matrix consisting of an aggregate of the ground carnauba wax having interconnecting voids therein, in which are embedded an intimate mixture of the active ingredient and filler (col.4, 1.17-21), wherein the tablet matrix forms a skeleton in the spaces of which the filler and active ingredient particles are distributed in mixed intimate relation (col.4, 1.28-33). Cain et al. teaches that each tablet consists of about 30.45% wax (i.e., understood to meet Applicant's "abuse-reducing amount" as recited in instant claim 1, absent factual evidence to the contrary and absent a specific definition by Applicant as to what constitutes an "abuse-reducing amount"); about 6.10% active ingredient; about 57.35% filler; and about 6.10% glucose (col.4, 1.22-24).

Though the cited prior art of Cain et al. is silent as to the claimed properties of (1) wherein crushing, compressing, fracturing, tumbling, rolling or milling of the controlled-release composition results in an increase in the aqueous dissolution of the active water soluble compound by less than about 15% of the total pharmaceutically effective amount of the active water soluble compound in the first hour of *in vitro* dissolution testing (claim 1) or (2) wherein crushing said matrix before contacting with water increases the aqueous dissolution of the active water soluble compound in said composition by less than about 10% of the total pharmaceutically effective amount of the active water soluble compound in the composition in the first hour of *in vitro* dissolution testing (claim 9), it is noted that the teaching of a composition with identical formulation components and characteristics (i.e., same active agents, same matrix, same structural relationships between the components, etc.) must necessarily possess the same functional properties of increasing the aqueous dissolution of the active water soluble compound when

Art Unit: 1614

subjected to crushing, etc., even though such properties may not have been appreciated by the patentee(s) at the time of the invention. This is because products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Thus, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims must necessarily be present, absent factual evidence to the contrary.

*In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions and/or properties that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function and/or property at the time of invention, so long as the function and/or property can be demonstrated to be reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though the cited prior art may not expressly teach the claimed properties of increasing the aqueous dissolution of the active water soluble compound when subjected to crushing, etc., the prior art clearly teaches a composition with identical formulation components and characteristics (i.e., same active agents, same matrix, same structural relationship between the components, etc.) and, therefore, these resultant properties must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, the cited prior art does not possess these same claimed characteristics.

Furthermore, though the cited prior art to Cain et al. teaches a composition physically and

Art Unit: 1614

structurally identical to that of the instant claims, the limitation of “for administration to a subject in need thereof from once to four times a day” (claim 11) is a clear statement of intended use of the composition as a whole and does not impart any physical or material characteristics to the composition that are not already present in the prior art. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the claim merely states, for example, a purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the limitation is of no significance to claim construction. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1554 and MPEP §2112.02(II). In the instant case, the cited prior art meets each and every structural and physical limitation of the instantly claimed composition and, thus, would be reasonably expected to be capable of performing the intended use as instantly claimed, absent factual evidence to the contrary and further absent any apparent structural difference between the composition of the cited prior art and that of the instant claims.

### ***Conclusion***

Rejection of claims 1, 4-5, 7, 9, 11, 24 and 40 is proper.

Claims 12-23 and 27-39 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-**

Art Unit: 1614

**MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/  
Primary Examiner, Art Unit 1614

October 14, 2010